I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON D.C. 20231 ON

October 12, 1999
DATE OF DEPOSIT

Robert A. Franks
REGISTERED REPRESENTATIVE

Robert A. Franks Oct. 12, 1999
SIGNATURE AND DATE OF SIGNATURE

PATENT
PD0586Q

L. TUCK
FG
10/21/99
1615

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Julianne Berry et al.

Serial No.: 08/920,611 — Group Art Unit: 1615

Filing Date: August 27, 1997 — Examiner: R. Bawa

Title: CHLOROFLUOROCARBON-FREE MOMETASONE FUROATE AEROSOL FORMULATIONS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

BRIEF ON APPEAL

This appeal is taken from the decision of the Primary Examiner mailed on March 9, 1999 in which claims of the subject application were finally rejected. Further to the Notice of Appeal filed on July 12, 1999, this appeal brief is being provided in triplicate: one bearing an original signature and two photocopies thereof. A petition for extension of time is enclosed, since the brief is not being filed within the prescribed period.

The Commissioner is hereby authorized to charge the $300.00 fee specified by 37 C.F.R. § 1.17(f) for filing a brief in support of an appeal, and any other fees which may be due in connection therewith, to our account. A Fee Transmittal sheet is enclosed, in duplicate, for that purpose.

10/20/1999 STEFERRA 00000044 190365 08920611
02 FC:120 300.00 CH

1. Real Party in Interest

The real party in interest in this appeal is Schering Corporation, assignee of the subject patent application by virtue of an assignment executed by the inventors.

2. Related Appeals and Interferences

There are no related appeals or interferences, which will affect or be affected by a decision in this appeal.

3. Status of Claims

The application was filed with claims 1-16. Claims 17 and 18 were added during prosecution (amendment filed September 28, 1998). Thus, claims 1-18 are the subject of this appeal.

4. Status of Amendments

All of the appellant's amendments have been entered; there was no amendment presented after final rejection.

5. Summary of the Invention

The presently claimed invention is an aerosol suspension composition for delivery of the corticosteroid drug mometasone furoate, the delivery to be accomplished by means of a metered dose inhaler, and a method of treatment involving administration of the composition. The composition contains, in addition to micron-size particles of the drug, the low-boiling propellant 1,1,1,2,3,3,3-Heptafluoropropane and ethanol, optionally further including a surfactant such as oleic acid.

The appealed claims all specify a relationship between the amount of drug present in the composition and the amount of ethanol present in the composition, as

the appellants have found a surprising adverse effect on the sizes of the suspended drug particles when the ethanol concentration is either too high or too low for the drug concentration. This adverse effect includes changes in the morphology and/or sizes of the drug particles during storage, unacceptably altering the drug delivery characteristics from those compositions which are not prepared in accordance with the limitations of the claims.

6. Issues

The sole issue of this appeal is as follows: have claims 1-18 been improperly rejected under the judicially-created doctrine of obviousness-type double patenting, because the applied patent does not show or predict any benefit from use of the claim-required narrow range of alcohol concentrations, and does not recognize the problem solved by the appellants' invention?

7. Grouping of Claims

It is submitted that the patentability issues for claims 1-18 are similar. The claims therefore are considered to stand or fall together.

8. Argument

Appellant's claims 1-18 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent 5,474,759 to Fassberg et al.

The Fassberg et al. patent relates to aerosol pharmaceutical compositions which utilize the non-chlorofluorocarbon propellant 1,1,1,2,3,3,3-Heptafluoropropane. Among the drugs described as being useful is mometasone furoate. This patent contemplates the optional inclusion in its compositions of "excipients" such as alcohols (and specifically mentions ethanol as being useful) and also optionally includes surfactants such as oleic acid or other substances. Claim ranges of excipient concentrations were broadly given as 0-75 wt.%, and more

narrowly 0-50 wt. %, while the concentration ranges for surfactants were broadly stated as 0-3 wt. %, 0-2 wt. % and 0-1 wt. %. Referring to the examples of the patent, none shows the specific combination of mometasone furoate, 1,1,1,2,3,3,3-Heptafluoropropane and ethanol, or any combination of these three ingredients with oleic acid or another surfactant.

The appellants' specification, at page 5, line 28 through page 6, line 24, describes a problem discovered by the appellants with storage stability in ethanol-containing mometasone furoate compositions. Summarizing this passage, it was found that the concentration of ethanol must be maintained at levels at least about 1 weight percent for predictable and consistent drug delivery, with higher amounts providing improvements in delivery. Also, it was found that unacceptable drug crystal growth in the compositions could be prevented by making the drug concentration at least about 1 percent of the ethanol concentration, which limitation functionally provides an upper limit for the ethanol concentration in any given formulation. These statements are fully supported by the examples, Example 2 showing the deleterious effect on drug delivery from decreasing the ethanol concentration, while Example 3 shows the effects on storage stability from varying the ratio of drug to ethanol.

It is immediately apparent that this stability problem, and the solution found by the appellants, was not recognized in the Fassberg et al. patent. The patent gives only the above-mentioned very broad ranges of excipient concentrations, starting at zero, and specifies the amounts of drug as 0.01-1 wt. %, preferably 0.03-0.7 wt. % and most preferred 0.05-0.5 wt. %. No information at all is provided concerning the possibility of interactions between the drug substance and the excipient. No information at all is given concerning storage characteristics of the compositions. No information at all is given concerning the specific critical formulation parameters of the appellants' claims.

Absent any relevant disclosure in the Fassberg et al. patent, no basis is evident for the statement in the final rejection that "there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a

patent." Any prior claiming of the invention was impossible, since the present invention is not disclosed in the prior patent. Disclosure of a broad range of ethanol concentrations cannot provide proper basis for claiming a specific narrow range.

The Final Rejection cites *In re Schneller*, 158 USPQ 210 (CCPA 1968) on this point. However, *Schneller* is concerned with a situation where a patent claimed one combination of elements and disclosed another, which was claimed in a copending application. This is not analogous to the present situation, where the applied patent does not identify either the problem discovered by the appellants nor any solution to that problem. The particular concentration parameters required by the appellants' claims are not found anywhere in the applied patent. *Schneller* is not applicable precedent for the rejection of appellants' claims and should be disregarded.

Similarly, the cited decision of *In re Bozek*, 163 USPQ 545 (CCPA 1969) does not support the rejection. The exact language from *Bozek* which is apparently being relied upon in the final rejection is found on page 549: "In any event, we have said many times that a reference disclosure must be evaluated for *all* that it fairly suggests and not only for what is indicated as preferred." The patent that was applied against the present claims discloses only broad concentration ranges and does not suggest that there are any differences between any two portions of any of the ranges. It does not suggest anything beyond those broad ranges. This decision is not relevant to the situation, and should be disregarded.

There is no teaching in the applied patent to the effect that use of any particular amounts of components within the broad ranges specified by the claims could yield a composition having unique properties. However, the appellants have unexpectedly discovered that compositions containing about 1 to about 10 weight percent ethanol and micronized mometasone furoate in concentrations at least about 1 percent of the ethanol concentration do have unique stability properties, as compared to compositions using ingredient concentrations outside these limits. This is clearly a result which could not be expected from the teachings of the patent, and negates any inference of obviousness.

CONCLUSION

In the absence of any reasonable basis to make out a case for obviousness, reversal of the improper final rejection of appellant's claims 1-18 is appropriate, and such action is respectfully solicited.

Respectfully submitted,

Robert A. Franks
Attorney for Appellants
Reg. No. 28,605

Patent Department K-6-1, 1990
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530
Telephone (908) 298-2908
Facsimile (908) 298-5388

APPENDIX - CLAIMS ON APPEAL

1. An aerosol suspension formulation comprising 1,1,1,2,3,3,3-Heptafluoropropane, about 1 to about 10 weight percent ethanol and micronized mometasone furoate in concentrations at least about 1 percent of the ethanol concentration, the formulation optionally also containing a surfactant.

2. The aerosol suspension formulation of claim 1, comprising about 1 to about 5 weight percent ethanol.

3. The aerosol suspension formulation of claim 1, comprising about 2 to about 5 weight percent ethanol.

4. The aerosol suspension formulation of claim 1, which contains a surfactant.

5. The aerosol suspension formulation of claim 4, wherein the surfactant comprises oleic acid.

6. The aerosol suspension formulation of claim 1, which is contained in a metered dose inhaler.

7. The aerosol suspension formulation of claim 1, which is contained in apparatus delivering a measured amount of about 10 to about 500 micrograms of mometasone furoate from a single actuating operation.

8. A method for treating allergic reactions in the respiratory tract, comprising administering by inhalation an aerosol suspension formulation comprising 1,1,1,2,3,3,3-Heptafluoropropane, about 1 to about 10 weight percent ethanol and micronized mometasone furoate in concentrations at least about 1 percent of the ethanol concentration, the formulation optionally also containing a surfactant.

9. The method of claim 8, wherein the suspension comprises about 1 to about 5 weight percent ethanol.

10. The method of claim 8, wherein the suspension comprises about 2 to about 5 weight percent ethanol.

11. The method of claim 8, wherein the suspension contains a surfactant.

12. The method of claim 11, wherein the surfactant comprises oleic acid.

13. The method of claim 8, wherein the suspension is contained in a metered dose container.

14. The method of claim 8, wherein the suspension is contained in apparatus delivering a measured amount of about 10 to about 500 micrograms of mometasone furoate from a single actuating operation.

15. A metered dose inhaler which contains an aerosol suspension formulation comprising 1,1,1,2,3,3,3-Heptafluoropropane, about 1 to about 10 weight percent ethanol and micronized mometasone furoate in concentrations at least about 1 percent of the ethanol concentration, the formulation optionally also containing a surfactant.

16. The metered dose inhaler of claim 15, wherein about 10 to about 500 micrograms of mometasone furoate are delivered from a single actuating operation.

17. The metered dose inhaler of claim 15, which is adapted for nasal delivery of mometasone furoate.

18. The metered dose inhaler of claim 15, which is adapted for lower airway delivery of mometasone furoate.